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U.S. COURT OF FEDERAL CLAIMS

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 17-564V

Filed: October 9, 2020

PUBLISHED

SUZANNE DEMITOR,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Special Master Horner

Shoulder Injury Related to Vaccine  
Administration; SIRVA; Table Injury;  
Causation in Fact; Tetanus  
Diphtheria acellular Pertussis (Tdap)  
Vaccine

*Suzanne Demitor, Walla Walla, WA, pro se.*

*Kimberly Shubert Davey, U.S. Department of Justice, Washington, DC, for respondent.*

### DECISION<sup>1</sup>

On April 25, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that as a result of her July 8, 2014 tetanus-diphtheria-acellular pertussis (“Tdap”) vaccination she suffered a Shoulder Injury Related to Vaccine Administration or “SIRVA,” which is an injury listed on the Vaccine Injury Table. 42 U.S.C. §300aa-14(a) as amended by 42 CFR § 100.3. On August 31, 2020, petitioner filed an amended petition. (ECF No. 65.) The amended petition further addresses the factual allegations underlying petitioner’s claim and does not specifically rely on the presence of Table Injury, though it does indicate that the injury “is consistent with a shoulder injury resulting from vaccine administration.” (*Id.* at 2.) The amended petition is construed as presenting a claim based in causation-in-fact. For the reasons described below, I conclude that petitioner is not entitled to compensation for her injury under either theory.

<sup>1</sup> Because this decision contains a reasoned explanation for the special master’s action in this case, it will be posted on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. See 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

## I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury.

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a “Table Injury.” That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the “Vaccine Injury Table,” corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a shoulder injury related to vaccine administration, or “SIRVA” as a compensable injury if it occurs within 48 hours of administration of a vaccine containing either tetanus toxoid or pertussis. §300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by a statutory “Qualifications and aids in interpretation” (“QAI”), which provides more detailed explanation of what should be considered when determining whether a petitioner has suffered an injury listed on the Vaccine Injury Table. (§300aa-14(a).) To be considered a Table “SIRVA” petitioner must show that her injury meets all of the following criteria:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; and
- (ii) Pain occurs within the specified time-frame; and
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §100.3(c)(10).

In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, of course, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see also *Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner may not receive a Vaccine Program award based solely on his or her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In what has become the predominant framing of this burden of proof, the *Althen* court described the "causation-in-fact" standard, as follows:

Concisely stated, *Althen's* burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

*Althen*, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be

consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Id.* at 1280.

In this case, petitioner initially alleged that her Tdap vaccine caused her to suffer the Table Injury of SIRVA. If petitioner’s injury meets the above-discussed definition of a Table SIRVA, she is entitled to a presumption of causation. Subsequently, petitioner filed an amended petition contending that her Tdap vaccine caused a shoulder injury without explicitly relying on the presence of a Table SIRVA. This latter claim must satisfy the above-described *Althen* test for establishing causation-in-fact without the benefit of any causal presumption. This decision will separately address each claim.

## II. Procedural History

As noted above, petitioner filed a petition alleging that she suffered a Table injury of “SIRVA” or “Shoulder Injury Related to Vaccine Administration” of her left shoulder on April 25, 2017. (ECF No. 1.) Based on the allegations in the petition, the case was assigned to the Special Processing Unit (“SPU”). (ECF No. 6.) The SPU “is designed to expedite the processing of claims that have historically been resolved without extensive litigation.” (*Id.* at 1.)

Petitioner initially supported her claim with the filing of medical records marked as Exhibits 1-4 and she filed a Statement of Completion on April 27, 2017. (ECF Nos. 7-8.) However, following the initial status conference, additional medical records marked as Exhibits 5 and 8 were later filed along with an affidavit by petitioner marked as Exhibit 6 and an affidavit by her husband marked as Exhibit 7. (ECF Nos. 10-11.) Petitioner filed a second Statement of Completion on June 27, 2017. (ECF No. 13.)

On October 17, 2017, respondent confirmed that he had completed a review of this case and indicated his intention to litigate. (ECF No. 16.) He later filed his Rule 4(c) Report on December 11, 2017. (ECF No. 17.) In his report, respondent raised a number of points based on his review of the medical records. Specifically, he contended that petitioner does not meet the criteria for a Table SIRVA because: (1) she had a history of “deep, aching bilateral mid-to-upper thoracic and cervical pain that was aggravated with overhead movements, reaching out, and repetitive use of the arms;” (2) “it is unclear whether petitioner’s pain occurred within 48 hours of vaccine administration;” (3) “when petitioner first presented for treatment after vaccination, she complained of left arm, neck and shoulder pain;” and (4) “petitioner had presented to a chiropractor on multiple occasions from 2011 through 2013 for segmental cervical dysfunction with muscle spasm and symptoms exacerbated with shoulder and arm movement.”<sup>2</sup> (*Id.* at 7-8.)

The case was subsequently removed from the SPU and reassigned at random to Special Master Millman on December 22, 2017. (ECF Nos. 19-20.) On January 31,

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<sup>2</sup> Although petitioner did not specifically plead an alternate cause-in-fact claim, respondent contended that petitioner would fail the *Althen* test for similar reasons. (See ECF No. 17, pp. 8-9 (citing *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)).)

2018, Special Master Millman held a status conference with the parties. (ECF No. 22.) Due to her anticipated retirement, she advised that “this case needs a factual hearing which will not be scheduled until it is reassigned to another special master.” (ECF No. 22.) No further action was taken in this case until it was reassigned to me on June 4, 2019. (ECF Nos. 24-25.)

On June 6, 2019, I issued a Scheduling Order informing the parties that I intended to hold a video fact hearing in this case during the week of July 15, 2019. (ECF No. 26.) Once the parties selected a hearing date, the parties were advised that the prehearing evidentiary record would close on July 8, 2019. (ECF No. 28.) No further evidence was filed. The video fact hearing was held on July 16, 2019. Petitioner and her husband testified. (See ECF No. 36, Transcript of Proceedings (“Tr”), July 16, 2019). Subsequently, petitioner was ordered to file additional records that were identified during the hearing. (ECF No. 33.) These records were filed on September 5, 2019 as Exhibits 10-14. (ECF No. 37.)

I issued a Finding of Fact on October 9, 2019. (ECF No. 38.) I found not only that petitioner’s alleged shoulder pain did *not* begin within 48 hours of vaccination, but also that the evidence preponderates in favor of finding that petitioner’s alleged shoulder injury began more than five months following her vaccination. Specifically, I found that “the chronic shoulder pain constituting petitioner’s alleged SIRVA, more likely than not, began in late December of 2014, more than five months following the date of her July 8, 2014 Tdap vaccination.” (*Id.* at 12.) I also found that “even if petitioner’s shoulder pain was temporally related to her Tdap vaccination, there is not preponderant evidence that her ‘pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered’ as required by the QAI for SIRVA.” (*Id.* at 16.) Accordingly, petitioner did not present a Table SIRVA.

Nonetheless, because petitioner had not pled any cause-in-fact claim, I provided petitioner a period to determine whether she would be able to reasonably amend her petition to pursue such a claim. (ECF No. 38, p. 16.) I advised, however, that petitioner should move to dismiss her claim if she did not have a reasonable basis to proceed in light of my Finding of Fact. (*Id.*)

On November 12, 2019, petitioner filed a status report advising that she intended to retain an expert to provide an opinion supporting her claim. (ECF No. 40.) However, petitioner did not explain on what basis she would proceed. I set a deadline for petitioner to file her expert report, but again cautioned that my prior Finding of Fact made it very unlikely that petitioner had any basis to proceed. (ECF No. 41.) I stressed that she will be required to show a temporal relationship between vaccination and injury and noted that I would not find persuasive any expert opinion that sought, contrary to my resolution of the facts, to rely on the presence of shoulder pain existing prior to December of 2014, some five months post-vaccination. (*Id.*)

On December 12, 2019, petitioner moved for an extension of 30 days to determine how she wished to proceed, which I granted. (ECF No. 42.) However, at the



time of that deadline, on January 13, 2020, petitioner's counsel filed a motion seeking to withdraw as counsel, indicating that "[c]ounsel has discussed with Petitioner how he recommends proceeding in this case. Petitioner and the undersigned disagree as to the best manner of moving forward with her case." (ECF No. 44.) I granted that motion also.

On March 16, 2020, I issued a detailed scheduling order giving petitioner instructions on how to proceed as a *pro se* litigant and, in light of my Finding of Fact, explaining her burden of proof under a cause-in-fact analysis. (ECF No. 55.) I explained that petitioner would need to file an expert medical opinion supporting her claim of vaccine causation that remained consistent with the facts of the case as I had found them. (*Id.* at 5-6.) Petitioner subsequently sought, and was granted, multiple extensions of time. (ECF Nos. 58-62.) In seeking additional time, petitioner questioned whether she could challenge my fact finding by filing additional evidence instead of filing an expert report. (ECF No. 61.)

On June 12, 2020, I advised as follows: "none of my orders issued to date have restricted the materials that petitioner may file. Accordingly, in addition to the amended petition and expert report identified in my March 16, 2020 Scheduling Order, petitioner is encouraged to file any and all material she reasonably believes will support her case. However, filings consistent with the instructions in my March 16, 2020 Scheduling Order will likely be the most productive." (*Id.*)

On July 23, 2020, I set a deadline of August 24, 2020, for petitioner to complete her filings to support a causation-in-fact claim. (ECF No. 62.) By that time, petitioner had already been allowed nine months since the issuance of my Finding of Fact to determine how she would proceed. I informed petitioner that no further extensions will be granted. (*Id.* at 2.) I further advised petitioner that she "should file her amended petition and whatever additional evidence she sees fit prior to that deadline . . . but she should not assume that she will be provided any subsequent opportunity to later file an expert report. After August 24, 2020, I will issue a decision resolving entitlement in this case based on the allegations contained in the original petition, or any amended petition, and the entirety of the record as it exists as of that date." (*Id.*)

Petitioner initially missed her August 24 filing deadline but filed a motion for leave to file out of time on August 27, 2020. (ECF No. 63.) I granted petitioner's motion and instructed her to complete her filing by no later than August 31, 2020. (ECF No. 64.)

On August 31, 2020, petitioner filed an amended petition along with additional documents marked as Exhibits 1-5. (To distinguish these exhibits from those previously filed by former counsel using the same designations, these five exhibits will be referred to herein as "*Pro Se Ex.*"). These exhibits include a letter from petitioner's chiropractor (*Pro Se Ex.* 1); Chart note amendments by the chiropractor (*Pro Se Ex.* 2); a Vaccine Adverse Event Reporting system on-line report (*Pro Se Ex.* 3); and two affidavits by petitioner (*Pro Se Exs.* 4-5). Petitioner did not file any expert report.

Special masters “must determine that the record is comprehensive and fully developed before ruling on the record.” *Kreizenbeck v. Sec’y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); see also Vaccine Rule 8(d); Vaccine Rule 3(b)(2). The parties must have a full and fair opportunity to present their case and develop a record sufficient for review. *Id.* In light of all of the above, and upon review of the entire record, I conclude that petitioner has had a full and fair opportunity to develop the record of this case and that the case is ripe for resolution on the existing record.

### III. Factual History<sup>3</sup>

#### a. As Reflected in the Medical Records

##### 1. Pre-Vaccination Condition

In the three-year period immediately preceding her alleged injury-causing Tdap vaccination, petitioner saw her primary care provider only twice. On April 29, 2011, she presented with a chief complaint of heart palpitations. (Ex. 2, pp. 1-3.) At that time her medical history was noted to include allergic rhinitis (improved) and pyelonephritis<sup>4</sup> in 2008, as well as prior surgeries including appendectomy, cesarean section, and tubal ligation. (*Id.* at 1-2.) No musculoskeletal complaints were noted and musculoskeletal exam notations were limited to “no deformity or scoliosis noted of thoracic or lumbar spine.” (*Id.* at 1.)

On May 23, 2011, petitioner returned to her primary care doctor for an annual exam. (Ex. 2, pp. 3-12.) She was reportedly feeling well and had no complaints at this visit. (*Id.* at 6-7.) Her musculoskeletal exam noted as follows: “Denies muscle cramps, joint pain, joint swelling, presence of joint fluid, back pain, stiffness, muscle weakness, arthritis, gout, loss of strength, muscle aches, chronic neck pain, and chronic back pain.” (*Id.* at 5.)

No further primary care records from this period have been filed in this case. However, petitioner subsequently began visiting a chiropractor on September 23, 2011.<sup>5</sup> (Ex. 4, p. 1.) At that time, petitioner had a chief complaint of “lumbosacral junction and left sacroiliac joint region(s) – aching pain.” (*Id.*) She had an additional complaint of “bilateral (but more intense on the left) upper thoracic and cervical region – aching pain and spasm.” (*Id.*) Petitioner indicated that the problem began on September 16, 2011,

<sup>3</sup> Within this section, sub-sections (a) and (b) reflect verbatim the same review of the facts of this case as included in my prior, October 9, 2019 Finding of Fact, which comprehensively examined all of the evidence filed in the case to that date. Petitioner’s subsequently filed materials are separately addressed in subsection (c).

<sup>4</sup> Pyelonephritis is inflammation of the kidney and renal pelvis due to bacterial infection. *Dorland’s Illustrated Medical Dictionary*, 32nd Ed., p. 1559.

<sup>5</sup> The record of petitioner’s September 23, 2011 chiropractic visit indicates that she had prior treatment with the same chiropractor that had “provided complete relief.” The date of this prior treatment is not indicated; however, onset of the complaint for which she was being seen was listed as September 16, 2011. (Ex. 4, p. 1.)

and that she “attributes the problem to exercising.” (*Id.*) Petitioner’s chiropractor diagnosed muscle spasms and segmental dysfunction of the sacral region as well as the lumbar, thoracic, and cervical levels. (*Id.*)

On May 9, 2012, petitioner returned to her chiropractor with essentially the same complaints. (Ex. 4, p. 3.) She noted that her lumbosacral and sacroiliac pain had been aggravated approximately a week earlier with no identified reason. (*Id.*) With regard to her bilateral mid thoracic to cervical pain, she rated her pain intensity as a three on a one to ten scale but noted pain of six out of ten when aggravated. (*Id.*) She indicated that her condition was “aggravated with overhead movements of the arm, reaching out with the arm and repetitive use of arms.” (*Id.*) However, the record notes that she “denies radiation of symptoms into the arms.” (*Id.*) At this time, the pain was noted to be more intense on the right. (*Id.*)

At this time, petitioner’s chiropractor tested her cervical range of motion. He recorded “active extension, right lateral bend and right rotation restricted 15% with tension locally 4/10.” (Ex. 4, p. 3.) He also noted “cervical compression with lateral bending right – with moderate pressure – produce pain locally – produce tension locally 5/10.” (*Id.* at 4.) To his previous assessment, the chiropractor added “neck sprain/strain” to his assessment along with sprain/strain of the thoracic, lumbar, and sacrum. (*Id.*)

Petitioner returned to the chiropractor again on August 17, 2012. (Ex. 4, pp. 6-8.) Petitioner’s complaints and the chiropractor’s findings and assessment were unchanged, but a progress note indicated “The condition has exacerbated, but unsure why?” (*Id.* at 7.) She returned again three days later on August 20, 2012. (*Id.* at 9-13.) Her record was again substantially the same, but this time noted that “[t]he patient reports feeling worse since the last visit but has been ill and not feeling well overall.” (*Id.* at 9.) On March 20, 2013, petitioner was seen by the chiropractor again. No additional notation was added to her record. (Ex. 4, pp. 14-16.)

## **2. Alleged Injury-Causing Vaccination**

On July 8, 2014, petitioner received a tetanus-diphtheria- acellular pertussis (“Tdap”) vaccination in her left deltoid as the Walla Walla County Health Department in Walla Walla, Washington. (Ex. 1, p. 5; Ex. 5, p. 3.) She returned two days later and received a measles, mumps, and rubella (“MMR”) vaccination in her right arm on July 10, 2014. (Ex. 1, p. 5; Ex. 5, p. 3.) Petitioner’s screening questionnaire for her MMR vaccination indicates that she has not had a serious reaction to a vaccine in the past. (Ex. 5, p. 7.) However, petitioner denies that this is accurate. (Ex. 6, p. 3.) Petitioner did not seek any medical care for any reason for the remainder of calendar year 2014.

## **3. Post-Vaccination Condition and Treatment**

On January 23, 2015, petitioner returned to her chiropractor approximately six months after her July 2014 vaccinations. (Ex. 4, pp. 17-18, 21-22.) At that time,



petitioner filled out a patient intake form. She listed her current complaints as “[left] arm pain, neck, shoulder.” (*Id.* at 21.) She listed the date of onset as “1 month” and for probable cause questioned “nerve?” (*Id.*) For “History of current complaints” she marked “none.” (*Id.*) Petitioner also marked “none” when prompted to list “all significant trauma.” (*Id.*)

The chiropractor characterized petitioner’s symptoms as “mid back through upper neck region left.” (Ex. 4, p. 17.) He recorded the following on examination:

Neck, upper mid back, left shoulder blade, and left upper posterior arm exhibits Asymmetry/Misalignment of moderate departure from center, or neutral, in relation to adjacent structures, palpatory Pain/Tenderness of moderate intensity, Range of Motion abnormality (hypomobile relative to patient) of moderate degree, and Tissue/Tone changes (hypertonic relative to patient) – left paracervical and left parathoracic, of moderate intensity.

(*Id.*) Petitioner was diagnosed as having “subluxation/nonallopathic lesion (segmental dysfunction)” of both the cervical and thoracic region as well as muscle spasm. (*Id.*) The chiropractor opined that the subluxations<sup>6</sup> he observed during the examination “are capable of producing the complaints described” by petitioner. (*Id.*)

On January 26, 2015, petitioner returned to the chiropractor. She reported “some improvement in symptoms since last visit.” (Ex. 4, p. 19.) Her subjective report indicated “mid back through upper neck region left: moderate, frequent, getting better since last visit, complaint grade 5 on a scale from 0 to 10.” (*Id.*)

Petitioner returned again to the chiropractor on March 4, 2015. (Ex. 4, pp. 26-27.) At this visit, petitioner reported “a return of symptoms or increase of complaints since last visit. She stated: ‘Lt. shoulder at subacromial area pain following vaccination on 7/8/14 persisting without relief from treatment.’” (*Id.* at 26.) However, the chiropractor still listed petitioner’s symptoms as “mid back through upper neck region left: moderate-severe, constant, remains unchanged since last visit, complaint grade 7 on a scale from 0 to 10.” (*Id.*) The chiropractor’s assessment remained unchanged, but he noted that petitioner “is not responding to treatment as expected.” (*Id.*)

Petitioner did not seek any further medical treatment until nine months later; however, a note within petitioner’s medical record from the Walla Walla County Health Department dated November 9, 2015 indicates as follows:

Client here today requesting and is given her immunization record. She also is requesting information regarding a stated reaction to her Tdap vaccine that she received on 7-8-14. She states that when she came in on 7-10-14 to receive her MMR vaccination that she had c/o red, hot and

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<sup>6</sup> In medicine “subluxation” generally refers to an incomplete or partial dislocation; however, specific to the chiropractic context, subluxation refers to “any mechanical impediment to nerve function.” *Dorland’s Illustrated Medical Dictionary*, 32nd Ed., p. 1791.

painful L arm after receiving her Tdap vaccine. She states that the nurse who saw her in clinic that day gave her ice packs and advised her to use Benadryl cream and continue with the cold packs and to take Tylenol or ibuprofen and to see her PCP or RTC if sx worse or did not improve, to which she further states that the “redness went away in about 1 wk[”] and the initial pain took “about 2 wks to go away” and then it all resolved. She states that with exercise it got worse “then it seemed to get worse and it went in to my neck 1<sup>st</sup> and then in to my shoulder.” “I lost my job 18 months ago and I have no insurance and no money of my own.” I saw a chiropractor “probably about 3 x” since 7-10-14. “I don’t know if the pain is triggered by too much exercise or housework. The pain radiates down my arm and every morning when I get dressed it hurts affecting my daily life.” “I don’t believe in vaccines. I only did this for immigration to save my husband \$750.00. My children are not vaccinated.” She is given the Tdap VIS information sheet and advised that this is generally a local reaction to the vaccine. She denies any axillary lymph node swelling at the time of vaccine. She states that she has been talking to a navigator at AHMG and she may see Dr. Hudson, an orthopaedic physician for a consult. She is referred to SOS clinic for evaluation. RTC prn JSRN

(Ex. 5, pp. 8-9.)<sup>7</sup>

About a month later, on December 3, 2015, petitioner sought orthopedic treatment for the first time on a self-referred basis with a chief complaint of left shoulder pain. (Ex. 3, pp. 1-5.) At this visit, petitioner associated her shoulder pain to her July 8, 2014 vaccination. She reported that “[t]hat evening, following the injection, she began to having [sic.] left arm swelling, redness and ‘terrible pain.’ The swelling and redness have decreased somewhat, though she continues to have these symptoms since the injection. Her pain is constant level 2-8/10.” (*Id.* at 1.) Petitioner also indicated that quick movements aggravate her symptoms and that she “has complaints of radiating pain to her hand, instability stiffness and weakness.” (*Id.*) The orthopedist also noted that “[s]he has had neck pain in the past, but not at this time.” (*Id.*) Petitioner’s symptoms were reportedly not improving and she noted two prior chiropractic visits “which were not helpful.” (*Id.*) Under the heading “orthopedic problems,” petitioner’s condition is listed as “neck, shoulder and arm.” (*Id.*)

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<sup>7</sup> Petitioner disputes the accuracy of this account. (Ex. 6, p. 3.) In her affidavit, she states that “the narrative is incomplete and incorrect;” however, she did not specify in what ways the account was inaccurate. (*Id.*) She noted that the facility would not change the record of her July 10, 2014 visit and that the nurse she spoke to had not been present at the time of her MMR vaccination. (*Id.*) In her hearing testimony, petitioner reiterated these concerns. (Tr. 52-53, 105-06.) She agreed that she reported her redness to have resolved but disputed that she stated that all of her symptoms had resolved. She also disputed that she had attributed the condition to exercising, indicating instead that she had meant to indicate that exercising exacerbated her symptoms. (*Id.*) She testified that she could not recall what prompted her to seek out her vaccination record at that time. (Tr. 104-05.)

Orthopedic examination revealed no swelling, ecchymosis,<sup>8</sup> muscle wasting, or masses. (Ex. 3, p. 3.) Petitioner exhibited “[d]iffuse tenderness about the shoulder, not well localized to any specific area.” (*Id.*) Petitioner demonstrated left shoulder range of motion of 140 degrees forward flexion and 80 degrees abduction with mild to moderate pain at the extreme. She had internal rotation to T12 with mild to moderate pain at the extreme and external rotation of 45 degrees with only mild pain at the extreme. (*Id.*) She was positive for impingement signs, painful abduction arc and on cross arm adduction testing, but negative on supraspinatus testing. (*Id.*) X-ray imaging showed mild early degenerative changes of the acromioclavicular joint. (*Id.* at 4.)

In his assessment, the orthopedist characterized petitioner’s condition as “a chronic shoulder ache and nonacute flare.” (*Id.*) The orthopedist’s assessment indicated “left shoulder pain,” “biceps tendinitis on left,” and “subacromial tendinitis of left shoulder.” (*Id.*) He recommended an MRI but noted petitioner’s lack of medical insurance at that time. (*Id.*) He also noted that “[a]t this point in time she is wishing me to document her current symptoms and she is going to pursue insurance coverage. She feels her current symptoms are due to a condition called ‘SIRVA’ or ‘shoulder injury related to vaccine administration.’ I unfortunately have not heard that before and would have a difficult time speaking to that etiology.” (*Id.*)

Subsequently, on December 21, 2015, petitioner returned to her chiropractor. (Ex. 4, pp. 28-29.) Petitioner reportedly had a chiropractic adjustment, though the chiropractor noted that petitioner associates her condition to her vaccination and recommended orthopedic treatment. He characterized petitioner’s injury as “outside realm of chiropractic.”<sup>9</sup> (*Id.* at 28.)

On June 22, 2016, petitioner briefly resumed treatment with her chiropractor and completed a new intake form. (Ex. 11, p. 27.) In this form, petitioner reported that her arm and shoulder pain began on July 8, 2014, as a result of a Tdap vaccine received that day. (*Id.*) She noted December of 2014 to mark a turning point for the worse and described some of her prior treatment. (*Id.*) Petitioner returned on June 24, 2016. (*Id.* at 32-33.)

Petitioner returned to chiropractic care, again in early 2019. (Ex. 11, p. 14.) On January 4, 2019, she completed an additional updated intake form. (*Id.* at 16.) In this form, she indicated that her left shoulder pain began on July 8, 2014, and that the cause was her Tdap vaccine.<sup>10</sup> (*Id.*) She returned several times in January, February and July of 2019. (*Id.* at 1-17.)

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<sup>8</sup> “Ecchymosis” refers to “a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch.” *Dorland’s Illustrated Medical Dictionary*, 32nd Ed., p. 588.

<sup>9</sup> This record includes a description of positive findings on examination related to neck, upper mid back, and left shoulder; however, these findings are repeated verbatim from prior visits. (Ex. 4, pp. 28-29.)

<sup>10</sup> Petitioner again associated no trauma with her injury. (Ex. 11, p. 16.)

Additional records were filed regarding a wrist fracture occurring in late 2017 and an ankle injury in early 2019, but no mention is made of petitioner's shoulder condition. (Exs. 12-14.<sup>11</sup>)

### **b. As Reflected in Testimony**

Petitioner denied that she had any prior injury or mobility issue in relation to her left arm or shoulder prior to receiving her July 8, 2014 Tdap vaccination. (Ex. 6, p. 1; Tr. 7-9.) She indicated that hours after receiving the vaccination, she experienced redness, swelling, throbbing, and pain in her shoulder and further indicated that the pain was "ever present" since the date of her vaccination. (Ex. 6, pp. 1-2; Tr. 46.)

Petitioner indicated that she had never experienced this type of pain before and testified that she knew immediately that the vaccine caused her injury. (Ex. 6, pp. 1-2; Tr. 47.) She confirmed that the redness and swelling resolved over a couple weeks, but indicated that the pain persisted. (Tr. 17.) She testified that during the time from her vaccination until she first sought medical care from her chiropractor, she experienced what she called "dramatic" changes to her routine and indicated that she was "doing everything in my life to avoid feeling the pain escalate." (Tr. 19-20.)

Petitioner further reports that on July 10, 2014, she informed a nurse at the Walla Walla Health Department about the redness and swelling she experienced in her left arm when she returned there to receive her MMR vaccination. (Ex. 6, p. 2; Tr. 13-15.) She reports that she was told to use an icepack and take Benadryl and that the pain would go away in a few days. (*Id.*) She indicated that she treated with Advil and Benadryl, which provided only temporary relief, but further stated that "I had no medical insurance and felt I could not afford seeing a doctor for treatment, so I tolerated the pain the best I could. I also hoped the nurse at the Walla Walla Health Department was correct and the symptoms would go away with time." (Ex. 6, p. 2.)

Petitioner averred that "[w]ithin a week or two, I couldn't sleep at night and could not lift my arm up, to the side, or reach back hardly at all. The initial symptoms of redness, swelling, and throbbing pain did become less severe, but I continued to feel numbness, aching and tingling in my arm. I stopped exercising because of this condition." (Ex. 6, p. 2.) She also testified that she took a road-trip to visit a friend in Seattle about a week after her vaccination. (Tr. 16-17.) She recalled that her friend was concerned about her driving in light of her arm pain. (*Id.*)

Petitioner indicated, however, that "[i]n December, 2014, my husband and I flew to New York to visit relatives. Whether because of the bitter cold in New York or the flight or some other reason, the pain in my left arm greatly increase[d]. The pain radiated down the entire length of my arm." (Ex. 6, p. 2.) Petitioner testified that her trip to New York marked a distinct escalation in the intensity of her pain. She testified that

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<sup>11</sup> Exhibit 13 does include some records dated July 8, 2014; however, no encounter is indicated, and the admission diagnosis is noted as being for administrative purposes. (Ex. 13, pp. 1-6.)

during the trip she had to change her sleeping habits and was almost crying due to the pain. (Tr. 21-22.)

Thereafter, due to her inability to afford a physician, petitioner indicated that she began treatment with a chiropractor. (Ex. 6, p. 2.) She testified that the chiropractic visit was a response to the pain she experienced while traveling to New York. (Tr. 22.) She indicated that initially the chiropractic treatment reduced, but did not eliminate, her pain, but that her pain worsened after her third visit. (Ex. 6, p. 2; Tr. 26.) Petitioner indicated that she has a persistent “dull ache” in her left arm which is aggravated by certain activities. (Ex. 6, p. 2; Tr. 19, 24-25, 34-38.)

At some point during her course of chiropractic treatment, the chiropractor suggested that he felt something fluid-like in the area of petitioner’s bursa. (Tr. 26-27, 120.) Petitioner indicated that initially she did not want to discuss with her chiropractor her belief that her injury was vaccine-related, but later decided to discuss what she believed caused her injury. (*Id.* at 28-29.) During this period, petitioner also came to believe her condition would not improve and in early 2015 discovered the concept of SIRVA by Google search.<sup>12</sup> (*Id.* at 40, 63.)

Petitioner’s chiropractor recommended that she seek out an orthopedist. (Tr. 120.) However, after one visit, petitioner was unable to return because his office closed. (Tr. 43.)

Petitioner’s husband, Timothy Demitor, also provided testimony. (Ex. 7; Tr. 127-172.) He indicated that petitioner was generally in good health and did not previously have problems with her left shoulder, but that “within hours” of receiving her Tdap vaccination, she showed him how her left arm was swollen and red and complained that her arm hurt. (Ex. 7, p. 1; Tr. 128-29, 153-54.) Mr. Demitor also indicated that he was present at the time of petitioner’s July 10, 2014 MMR vaccination and that he witnessed petitioner report her redness and swelling to the nurse. (Ex. 7, pp. 1-2; Tr. 131-33.)

Mr. Demitor indicated that petitioner is not typically the type to complain, but he noticed that in the months after her vaccination she needed his help with lifting and vacuuming and that she was having trouble with her sleeping position. (Tr. 135-36.) He also recalled that petitioner complained a lot about her shoulder pain during their trip to New York in December of 2014. (*Id.* at 137.)

Mr. Demitor also “vaguely” recalled being present for a later conversation in about November of 2015 with the supervising nurse at Walla Walla County Health regarding whether petitioner’s vaccine record was complete. (Tr. 161-63.) However, he could not recall the details of that discussion beyond discussing the lack of a notation in the records regarding the recommendation to take Benadryl and anti-inflammatories. (*Id.*) He did recall, however, that around the time they discovered that Walla Walla County Health had not recorded the vaccine-reaction she reported on July 10, 2014, he

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<sup>12</sup> Petitioner testified that she was provided a vaccine information sheet at the time of her Tdap vaccination, but that she did not read it at the time. (Tr. 62.)



was able to discuss the issue with the nurse who administered the vaccine. (*Id.* at 139-142, 159-60.) He testified, however, that she would not volunteer any information and that, while she remembered that they came in for vaccinations, would not confirm that she remembered any details. (*Id.*) He indicated that when asked if she remembered, she would only say “well, that was a really long time ago.” (*Id.* at 141-42.)

**c. As subsequently reflected in petitioner’s August 31, 2020 filings**

On June 22, 2016, petitioner completed an online report of adverse event to the Centers for Disease Control and Prevention (CDC) through the Vaccine Adverse Events Reporting System (“VAERS”). (*Pro Se Ex. 3.*) Petitioner initially recorded a date of vaccination of July 14, 2014, but later within the submission sought to correct the date to July 8, 2014. (*Id.* at 2-3.) Petitioner described her injury as follows:

Initially immediately reacted with swelling, redness, soreness, numbness from the tips of my fingers. Reported to clinic two days later on 7/10/2014. Only one nurse was working that day and I later found out she did not record any notes. She did give me ice packs and told me to take [Benadryl]. For months had trouble with housework, working out, sleeping, chores. Soon thereafter the injury affected my arm movement. I found it hard to lift my arm. Seemed to improve but didn't go away. Greatly affected my life. At about 5 months the onset of extreme pain returned. It is now almost 2 years since vaccination date but I am still suffering from dull achy pain and have trouble sleeping as a result. I am still suffering. I have no medical insurance and this is really hard. Please note I do not know what time exactly I was given the vaccine. I do know that the onset of adverse reaction was pretty much immediate, say within an hour. I have entered 6:00 pm, as I this would have been at 1 hour after the clinic closed that day.

(*Id.*)

Petitioner indicates in her amended petition that sometime in 2017 she was asked by her former counsel to complete an affidavit explaining why she previously wrote in her January 2015 chiropractic intake form a “1 month onset” of her shoulder pain. (ECF No. 65, p. 4.) She represents that the affidavit was not filed, and was not available to her at the hearing, because her former counsel lost it. (*Id.*) The affidavit itself is undated. (*Pro Se Ex. 4.*)

In this affidavit, petitioner indicates that “[t]he ‘1 month’ onset mentioned on the chiro intake form for my first visit on 1/23/15 was referring to a 1 month at the current intensity level of pain I was feeling, making life unbearable – enough so to prompt me to see the chiropractor in hope he could fix the problem. I had just spent 12/24/14-1/12/15 in NY and my pain had become unbearable at that point, that I could not longer manage it, and I began to research for the first time vaccine injuries.” (*Pro Se Ex. 4*, p. 1.) Petitioner’s affidavit includes what appear to be screen captures or copies of e-mails she sent on February 26, 2015, one to herself with links to information regard vaccine-

related shoulder injuries and one to her former counsel describing her experience and seeking legal counsel. (*Id.* at 1-2.)

In an undated correspondence, petitioner's chiropractor indicated that he would like to amend his March 4, 2015 and December 21, 2015 notes to recharacterize Ms. Demitor's statements to him. (*Pro Se Ex. 2.*) Petitioner represents in her amended petition that these corrections were made in August of 2019 following the fact hearing. (ECF No. 65, p. 2.)

The contemporaneously-created March 4, 2015 record indicated: "Ms. Demitor reported a return of symptoms or increase of complaints since last visit. She stated: 'Lt. shoulder at subacromial area pain following vaccination on 7/8/14 persisting without relief from treatment.'" (Ex. 4, p. 26.) The proposed correction indicates "Ms. Demitor reported a return of symptoms since her last visit. The left shoulder subacromiac pain is persisting. This is the same area of complaint that followed the vaccination on 7/8/14." (*Pro Se Ex. 2*, p. 1.)

The contemporaneously-created December 21, 2015 record indicated: "Ms. Demitor reported a return of symptoms or increase of complaints since last visit. She stated: 'Vaccination that caused left shoulder problem persists. Recommend evaluation with orthopedist for ongoing condition. Shoulder condition was reported following the 7/8/14 vaccination. last visit was on 3/4/14. outside realm of chiropractic. Treatments following the 1/23/14. was for the associated lt shoulder complaint.'" (Ex. 4, p. 28.) The proposed correction reads: "Ms. Demitor reported a return of symptoms since her last visit. She stated, 'the left shoulder pain that was caused by the 7/8/14 vaccination is ongoing.' I recommend an evaluation with an orthopedist for this persisting shoulder condition that was reported following the 7/8/14 vaccination. This condition is outside the realm of chiropractic." (*Pro Se Ex. 2*, p. 1.)

Additionally, on August 24, 2020, petitioner's chiropractor wrote a letter indicating as follows:

The treatment for Ms. Demitor's upper back and neck areas were secondary to her shoulder complaints after the 7/8/2014 vaccination. Prior to 7/8/2014 her neck and upper back condition was episodic associated with exercising and activities of daily living. There did not appear to be any preexisting chronic neck, upper back or left shoulder conditions before the 7/8/2014 vaccination. There has been a consistency of left shoulder complaints following 7/8/2014. Ms. Demitor's shoulder condition is outside my area of expertise.

(*Pro Se Ex. 1.*)

In an additional affidavit dated August 31, 2020, petitioner indicates in reference to her January 2015 chiropractic intake form that "[i]t is evident from my scantily filled out form and messy writing that I did not have sufficient time to fill in the form. I hastily filled it out. I did not have enough time to complete it to my satisfaction ahead of my

appointment and I did not want to reduce my treatment time or keep the doctor waiting.” (*Pro Se Ex. 5*, p. 1.)

With regard to a specific reference on the intake form to “Nerve?,” petitioner indicated that she intended to indicate her belief that perhaps the needle used for her vaccination may have hit a nerve. (*Id.* at 1-2.) She indicated she was not aware of how the vaccine could have caused her injury. (*Id.*)

Petitioner indicated that in a section of the form related to current complaints, she included the word “neck” because her shoulder pain had caused her to sleep in an unnatural position that resulted in stiffness and tightness in the neck. (*Id.* at 2.)

Petitioner also indicated that she was initially afraid to disclose to her chiropractor that her injury was vaccine-related because she did not know his stance on vaccines. (*Id.*) She was concerned she might experience biased treatment and hoped she would receive effective treatment even while remaining vague as to the cause. (*Id.*)

#### **IV. Petitioner’s Additional Filings Do Not Alter the Prior Finding of Fact**

As noted above, I previously issued a Finding of Fact on October 9, 2019, following the fact hearing held in this case in July of 2019. (ECF No. 38.) Specifically, I held that:

- (1) “based upon my review of the entire record, I do not find preponderant evidence that petitioner’s alleged vaccine-caused shoulder pain began within 48 hours of her July 8, 2014 Tdap vaccination. Rather, I find that the chronic shoulder pain constituting petitioner’s alleged SIRVA, more likely than not, began in late December of 2014, more than five months following the date of her July 8, 2014 Tdap vaccination.” (*Id.* at 12.)
- (2) “even if petitioner’s shoulder pain was temporally related to her Tdap vaccination, there is not preponderant evidence that her ‘pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered’ as required by the QAI for SIRVA.” (*Id.* at 16.)

Although my findings were incompatible with a Table SIRVA as pled by petitioner, I did not close the record on entitlement at that time and provided petitioner an opportunity to file additional evidence relating to a causation-in-fact claim. However, petitioner opted instead to file evidence which she contends should have the effect of calling my prior Finding of Fact into question. Thus, because of the procedural history of this case, upon resolving entitlement I am now faced with a factual record that is not identical to the record upon which I based my Finding of Fact. Accordingly, in the interest of completeness, I will specifically address why petitioner’s subsequently filed evidence does not necessitate any change in that prior analysis for purposes of determining petitioner’s entitlement to compensation. My prior Finding of Fact incorporated significant additional analysis explaining how I reached these two

conclusions. Familiarity with that analysis is assumed and I will not repeat that full analysis in this decision.

**a. Onset of shoulder pain**

After discussing applicable caselaw regarding the balancing of contemporaneous medical records against subsequent testimony and considering the record as a whole, I explained in my Finding of Fact that petitioner's January 23, 2015 chiropractic record, which included a handwritten intake form, was "particularly persuasive" in dating the onset of petitioner's shoulder pain. (ECF No. 38, pp. 10-12.) That record placed onset of petitioner's shoulder pain at one month prior to that visit, or in approximately late December of 2014. (Ex. 4, pp. 17-18, 21.)

I indicated that there were a number of reasons why the record itself was worthy of significant weight. First, I explained that the January 23, 2015 record was the most contemporaneous treatment record and therefore reflects the most contemporaneous recollection available. Second, it was created with proper treatment hanging in the balance. Third, because it included a notation written by petitioner herself, the reported onset could not be attributed to paraphrasing or transcription error. And, fourth, the history reflected in the record could be read to be potentially consistent with the facts and circumstances reflected by the record as a whole. (ECF No. 38, pp. 12-13.) Upon review, I am not persuaded that any of petitioner's August 31, 2020 submissions contradict these considerations.

I also previously considered whether petitioner's testimony could outweigh that record. This included her testimony that she felt rushed when completing the form, her testimony that the report of a one-month onset actually reflected a worsening of her condition while she was travelling to New York, and her testimony that her specific reference to "nerve?" referred to her injection potentially having hit a nerve. (*Id.* at 13, n.12.) All of these are points re-raised by petitioner's August 31, 2020 filings and constitute the bulk of petitioner's substantive assertions relative to onset in those filings. Additionally, consistent with the later completed VAERS submission, I further considered petitioner's alternative narrative of events as recorded when she returned to the Walla Walla County Health Department in November of 2015. (*Id.* at 14.)

On the whole, I found in the prior Finding of Fact that petitioner's subsequent recollection lacked sufficient indicia of reliability to outweigh the contemporaneous record. (*Id.* at 15.) I noted in particular that petitioner's testimony was inconsistent and that at several points she needed to rely on or defer to the medical records themselves to recall events. (*Id.*) That petitioner has subsequently produced affidavits and a self-completed VAERS submission reiterating essentially the same points reflected in her testimony does not render the original, contemporaneous document less reliable. Nor does it significantly alter my weighing of the competing evidence, including her hearing testimony.

In fact, petitioner's latest submissions maintain, rather than resolve, the inconsistencies in petitioner's testimony and continue to cast doubt on the reliability of her recollections. For example, during the hearing petitioner acknowledged her difficulty recalling why she completed her chiropractic intake form in the manner that she did. (Tr. 23-24.) In her latest affidavit she now nonetheless purports over a year later to provide further details on her rationale for various notations. (*Pro Se Ex. 5.*) In her so-called lost affidavit of 2017, she indicates that she deliberately identified the onset of her condition on her chiropractic intake form based specifically on a worsening of her pain in December of 2014. (*Pro Se Ex 4*, p. 1.) In her new affidavit of 2020, she intimates that the incorrect placement of onset is due to her having completed the form in haste and her wanting to conceal the fact of her injury being vaccine-caused. (*Pro Se Ex 5*, p. 1.) These explanations are, if not contradictory, in tension, and both explanations were previously presented as part of petitioner's hearing testimony. (Tr. 94-96.)

Of note, none of the additional evidence presented by petitioner was created contemporaneous to the alleged time of onset of her injury and was instead created by her subsequent to her first seeking legal counsel to pursue this claim and, in some instances, subsequent to having testified during the fact hearing.<sup>13</sup> (*Pro Se Ex. 4*, p. 2.) To the extent she filed any additional materials authored by a disinterested party (namely her chiropractor), none of those materials speak directly to onset or meaningfully contradict the prior evidence of record with regard to onset. Contemporaneous records prepared independently of litigation are often more reliable than testimony of interested parties. See *Rogero v. Sec'y of Health & Human Servs.*, 748 Fed. Appx. 996 (Fed. Cir. 2018); *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993) (stating that "written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.").

#### **b. Symptoms not limited to shoulder**

I also previously found that petitioner's symptoms were not limited to the shoulder in which she received her vaccination. (ECF No. 38, p. 16.) I noted that petitioner consistently reported to her chiropractor that she had pain extending into her neck. (*Id.* (citing Ex. 3, pp. 1-5; Ex. 4, pp. 17, 19, 21, 26-27; Ex. 5, pp. 8-9).) She also

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<sup>13</sup> Petitioner's "lost" affidavit, which she indicates was drafted sometime in 2017, does incorporate reference to copies of e-mail exchanges from February of 2015. (*Pro Se Ex. 4.*) However, even if I considered these e-mails as evidence generated in 2015, when purportedly first sent, rather than 2017, when the affidavit was drafted, they still post-date her original chiropractic appointment, which itself was months after her vaccination and alleged onset of her injury. It has always been the case that the record reflects that at some point following her commencement of treatment for her shoulder injury she began reporting that her shoulder pain actually began at the time of her vaccination. Petitioner's 2017 affidavit suggests that she first sought advice of counsel on February 26, 2015. (*Pro Se Ex. 4*, p. 2.) Her next chiropractic appointment on March 4, 2015, was the first time she is recorded to have reported shoulder pain connected to her July 8, 2014 vaccination. (Ex. 4, p. 26.)



reported neck pain and pain radiating into her hand after concluding herself that she was suffering a SIRVA. (*Id.* (citing (Ex. 3, pp. 1-5; Ex. 5, pp. 8-9).)

Petitioner now seeks to call into question whether her chiropractor recorded meaningful complaints of neck pain. (*Pro Se Ex. 1*; ECF No. 65 (amended petition).) To the extent petitioner has provided a letter by her chiropractor seeking to recharacterize the history reflected by his much earlier records (*Pro Se Ex. 1*), I continue to find the prior records to be the most credible account. See, e.g., *Milik v. Sec'y of Health & Human Servs.*, 822 F.3d 1367, 1380-81 (Fed. Cir. 2016) (holding that the special master reasonably credited a physician's earlier diagnosis over a later, contradictory letter of clarification). The prior records include not only petitioner's own freshest recollection of her symptoms, but also contemporaneous observations from the chiropractor upon examination. (*Cf. Pro Se Ex. 1* and Ex. 4, pp. 3-4 (e.g. observing pain with cervical compression and lateral bending); Ex. 4, p. 19 (e.g. noting "[c]hiropractic manipulative treatment will be administered due to the finding of neck, upper mid back, and left shoulder blade segmental dysfunction" and "Ms. Demitor responded favorably to her treatment today . . .").) In any event, although he now characterizes it as secondary, the chiropractor's letter does still confirm treatment of post-vaccination symptoms relating to the neck and upper back. (*Pro Se Ex. 1*.)

Moreover, as noted in my prior Fact Finding, petitioner also reported neck pain to her orthopedist when she sought orthopedic care specifically for her shoulder pain. Nothing in her August 31, 2020 filings addresses or contradicts that record. (ECF No. 38, p. 16 (citing Ex. 3, pp. 1-5).) Moreover, petitioner filed an earlier affidavit in this case averring that she had neck pain and pain radiating down her arm. (Ex. 6, pp. 2-3.) In her latest affidavit, petitioner likewise acknowledges the presence of soreness, tightness and stiffness in her neck during this period, though she attributes them to an unnatural sleeping position brought about by her shoulder injury. (*Pro Se Ex. 5*.)

## **V. SIRVA Table Injury**

For all the reasons discussed above and in my prior Finding of Fact, I have found that there is not preponderant evidence that onset of petitioner's shoulder pain occurred within 48 hours of her July 8, 2014 Tdap vaccination. I have also found that there is preponderant evidence that petitioner's symptoms were not limited to the shoulder in which she received her vaccination. Accordingly, petitioner has not met her burden of proof with respect to a Table Injury of SIRVA as these findings prevent her from satisfying the QAI definition of SIRVA. 42 C.F.R. §100.3(c)(10).

## **VI. Shoulder Injury Caused-in-Fact by Vaccination**

Although petitioner is not entitled to a presumption of causation for a Table SIRVA, she may nonetheless prove that her injury was in fact caused by her vaccination. However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

Here, none of petitioner's medical records support vaccine-causation. Although petitioner's chiropractor seems to have indicated that he is receptive to the idea of vaccine-causation, he explicitly disclaimed any ability to treat or assess petitioner's shoulder condition. (Ex. 4, p. 28 (referencing petitioner's complaint of post-vaccine shoulder problems as "outside the realm of chiropractic"; *Pro Se* Ex. 1 (noting "Ms. Demitor's shoulder condition is outside my area of expertise.")).) Moreover, he has not set forth any opinion addressing how the vaccination could have caused petitioner's injury or why he would have reached that conclusion. Petitioner did visit an orthopedist; however, that orthopedist did not opine that petitioner's injury was vaccine-caused and, in fact, disclaimed any knowledge of SIRVA and declined to speak to a vaccine-related etiology for petitioner's condition. (Ex. 3, pp. 3-4.)

I additionally provided petitioner approximately ten months to locate an expert who could provide a medical opinion supporting causation consistent with the facts of this case as I have found them. She filed no expert opinion.

Accordingly, petitioner has not met her burden of proof with respect to demonstrating that her injury was caused-in-fact by her vaccination. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). More specifically, she has not submitted any evidence (either within her medical records or in any expert report) asserting a theory of vaccine causation in the absence of a Table presumption of causation (*Althen* prong one). Nor in the absence of any expert medical opinion do her medical records support a logical sequence of cause and effect suggesting her vaccination as the cause of her injury (*Althen* prong two). Nor has she established that onset of her condition is consistent with a proximate temporal relationship between vaccination and injury (*Althen* prong three).

## **VII. Conclusion**

Petitioner has my sympathy for the pain and suffering she endured during what must have been a very difficult period in her life and I do not doubt her sincerity in bringing this claim. However, for all the reasons discussed above, after weighing the evidence of record within the context of this program, I cannot find by preponderant evidence that petitioner's injury was caused by her July 8, 2014 Tdap vaccination as alleged. Therefore, this case is dismissed.<sup>14</sup>

**IT IS SO ORDERED.**

**s/Daniel T. Horner**

Daniel T. Horner  
Special Master

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<sup>14</sup> In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.